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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HORNING, MICHELLE S	

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1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,891	BENSCIK-REYNIER ET AL.	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/24/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to communication filed 4/18/2008. The status of the claims is as follows: claims 1-17 are under current examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a step of detecting the PrP in a biological sample. For example, claim 1 has no active steps, in that, this claim merely recites that the method "uses a molecule..." but has no steps of combining the sample with said molecule, as well as, steps required for the actual detection thereof. While the dependent claims include some active steps necessary for the claimed method of detection, none of the claim include a step which actually accomplishes the detection of the PrP. While claim 4 recites a "revealing" step, it is unclear how this step is used for the detection of the PrP. Thus, none of the dependent method claims include a step to detect the PrP in a sample and fall therewith.

Claim 5 recites the limitation "the PrP aggregates" in lines 4 and 5. There is insufficient antecedent basis for this limitation in the claim. It is unclear if this recitation refers to the infectious aggregated form of prion proteins or an aggregate

formed from step b of claim 4. However, since claim 4 includes formation of an aggregate, changing the dependency of claim 5 from "claim 1" to "claim 4" will overcome this rejection.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 is confusing as it refers to a "step d". However, this claim is dependent on claim 1. Of note, claim 1 has no step d. Although unclear, it appears that this claim should be dependent on claim 4. Appropriate correction or further elucidation is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 and 15-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation of “a molecule having at least one positive charge and/or at least one glycosidic bond” is not described in the specification in a reasonably generic manner to show that applicant envisioned the scope of this broad recitation at the time of filing. The specification

describes a very limited number of specific compounds that are encompassed by said recitation. However, due to the broad genus encompassed by the recitation, which would include any and all cationic compounds, combined with the description in the specification of only a limited number of specific compounds, which are neither related in structure nor function, this limited description fails to provide adequate support for the genus of molecules defined as only requiring a positive charge. Given that many molecules have either a positive charge or a glycosidic bond, the claim requires that the molecule is useful for PrP detection. The specification, however, provides no structural to functional correlation (i.e. which cationic molecules will work). Please note that this recitation is also not a term of art as to provide a clear indication that applicant envisioned this generic concept at the time of filing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Godfried Andre Van Kruchten (US 6,137,014). The '014 patent discloses a product comprising a macrocyclic ligand which is bound to a solid support; see claim 4. The product also includes a molecule having a positive charge, such as, an alkali metal, see column 5, lines 5+. It is noted that the recitation of "A diagnostic kit for detecting PrP"

has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Claims 1, 2, 6, 9 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Lansbury (US 6,054,114). The '114 patent discloses a method of detecting the presence of prion protein in biological samples; see abstract and column 47, lines 11+. The method comprises adding an amyloid binding compound of the formulae shown in columns 2-7, which include macrocyclic chelating agents (column 3). The recitation of "as to precipitate the PrP" would inherently occur, since the method of the '114 patent includes the same steps. These macrocyclic chelates would themselves also meet the limitation of a molecule having a positive charge, due to the use of various positively charged metals, Fe, etc., see column 2, lines 40-45. It is noted that while oxo forms of the metal are preferred, they are not required. The compositions comprises the chelating agent would be packaged for diagnostic use and therefore would meet the limitation of a kit, as set forth in claim 16. The recitation of claim 6 is met, because this claim is dependent on claim 1, which only further includes a PrP

specific binder partner, which is also encompassed by the compounds used in the methods of the '114 patent, see abstract.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lansbury (US 6,054,114) in view of Kiesewetter (WO 02/065133, US 2004/0096902 relied on as a US equivalent). The '114 patent discloses a method of detecting the presence of prion protein in mammals or in biological samples (*in vitro* methods), which comprises adding an amyloid binding compound of the formulae shown in columns 2-7, which include macrocyclic chelating agents (column 3)., as discussed above.

The '114 patent fails to teach that the *in vitro* methods of detecting PrP include the use of the binding principles, such as, glycoaminoglycans (GAGs), etc., adding proteinase K, separating and denaturing PrP aggregates, and that the binding reactant(s) are bound to a solid support.

The '902 patent disclose a method of detecting PrP in biological samples which comprises the use of a detection compound that binds PrP, thus, the methods are in the same field of endeavor as the '114 patent. The '609 patent used the same compounds encompassed by the instant claims are a PrP binding principle, including GAGs; see page 2. The '902 patent teaches a method wherein the PrP is first treated with proteinase K, as a denaturant, that the ligand is bound to a solid support, separating the denaturing PrP aggregates and detecting them in the sample using, for example a fluorophore; see page 2.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods disclosed in the '114 patent to use a PrP specific binding partner, such as a GAG because the '902 patent specifically teaches that these compounds are very effective PrP binding principles for *in vitro* detection methods, due to their high affinity for these proteins and ability to remove the PrPsc from the sample. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further include the additional steps of adding proteinase K to the sample, employing a solid support for the binding reactant(s) and separating the PrP therefrom, in the methods of the '114 patent, because the'902 patent teaches that these steps allow for a simple, rapid and effective i*n vitro* assay for

detecting of PrP. One of ordinary skill in the art would have been motivated to look at known and effective methods of performing in vitro assays for PrP, such as, disclosed by the '902 patent, when performing endeavors in the *in vitro* assays for PrP detection generally disclosed in the '114 patent. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 7,217,530 in view of Kiesewetter (WO 02/065133, US 2004/0096902 relied on as a US equivalent). Although the conflicting claims are not identical, they are not

patentably distinct from each other because many of the instant clams are generic to the specific methods set forth in the claims of the ‘530 patent. For example, instant claim 1 only requires the use of a macrocyclic chelating agent in the method, which is clearly set forth in claim 1 of the '530 patent by the use of the AML. The instant claims do not exclude the additional steps set forth in the claims of the '530 patent. Thus, the patented claims fall completely within the genus of the instantly claimed method. However, some of the instant dependent claims include limitations which are not set forth in the claims of the ‘530 patent. For example, the claims of the ‘530 patent do not include adding proteinase K, separating and denaturing PrP aggregates, and that the binding reactant(s) are bound to a solid support.

The ‘902 patent disclose a method of detecting PrP in biological samples which comprises the use of a detection compound that binds PrP, which are similar to methods in the ‘530 patent. The '902 patent teaches a method wherein the PrP is first treated with proteinase K, as a denaturant, that the ligand is bound to a solid support, and separating the denaturing PrP aggregates and detecting them in the sample, which provides the advantage of an effective reaction assay; see page 2

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods disclosed in the '530 to further include the additional steps of adding proteinase K to the sample, employing a solid support for the binding reactant(s) and separating the PrP therefrom, in the methods of the '530 patent, because the’902 patent teaches that these steps allow for a simple, rapid and effective *in vitro* assay for detecting of PrP.

Claims 1-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-22 of copending Application No. 11/701,334 in view of Kiesewetter (WO 02/065133, US 2004/0096902 relied on as a US equivalent). Although the conflicting claims are not identical, they are not patentably distinct from each other because many of the instant clams are generic to the specific methods set forth in the claims of the '334 application. For example, instant claim 1 only requires the use of a macrocyclic chelating agent in the method, which is clearly set forth in claim 1 of the '334 application by the use of the AML. The instant claims do not exclude the additional steps set forth in the claims of the ''334 application. Thus, the patented claims fall completely within the genus of the instantly claimed method. However, some of the instant dependent claims include limitations which are not set forth in the claims of the '334 application. For example, the claims of the '530 patent do not include adding proteinase K, separating and denaturing PrP aggregates. The '902 patent disclose a method of detecting PrP in biological samples which comprises the use of a detection compound that binds PrP, which are similar to methods in the '530 patent. The '902 patent teaches a method wherein the PrP is first treated with proteinase K, as a denaturant, and separating the denaturing PrP aggregates and detecting them in the sample, see page 2.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods disclosed in the ''334 application to further include the additional steps of adding proteinase K to the sample, and separating the

PrP therefrom, in the methods of the "334 application, because the'902 patent teaches that these steps allow for a simple, rapid and effective *in vitro* assay for detecting of PrP.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michelle Horning/
Examiner, Art Unit 1648

/Bruce Campell/
Supervisory Patent Examiner, Art Unit 1648